

What is claimed is:

1. A method for tracking cells *in vivo*, the method comprising the steps of:

- (a) isolating and purifying stem cells from a subject;
- (b) providing a chemically heteroconjugated bispecific antibody with a binding site specific for a stem cell antigen and a binding site specific for a target antigen in a patient; and,
- (c) arming the stem cells with the bispecific antibody under conditions wherein;
 - (i) the bispecific antibody binds to the stem cells via the c-kit ligand; and,
 - (ii) the second antigenic binding site of the bispecific antibody is free to bind to the target antigen; and,
 - (iii) binding of a labeled antibody to the Fc region of the bispecific antibody; or,
 - (iv) fluorescently labeling the bispecific antibody thereby a secondary labeled antibody is not required; and,
- (d) reinfusing the armed and labeled stem cells into a patient; and,
- (e) tracking the armed and labeled stem cells by extracting blood and/or tissue samples from the patient at different time intervals; and,
- (f) identifying the armed and labeled cells by phenotyping the cells using flow cytometry cell sorting; and,
- (g) identifying the armed and labeled cells by immunohistochemical staining or other methods to detect the primary antibody on the cells in various target tissues such as bone marrow, spleen, liver, pancreas, lungs, neural tissue, gastrointestinal track, heart, vascular endothelium.

2. The method of claim 1, wherein the bispecific antibody is specific for c-kit ligand of stem cells and myocardial antigens.

3. The method of claim 2, wherein the bispecific antibody is specific for myocardial VCAM-1, NCAM-1, PECAM.

4. The method of claim 1, wherein secondary antibody, binding to the Fc region of the bispecific antibody, is fluorescently labeled.

5. The method of claim 1, wherein the bispecific antibody is directly fluorescently labeled.

6. The method of claim 1, wherein the armed and labeled stem cells home to, and bind to the target tissue antigens.

7. The method of claim 6, wherein the stem cells accumulate at the target antigen site.

8. The method of claim 7, wherein the stem cells differentiate into cells typical of the targeted tissue or organ.

9. The method of claim 1, wherein the patient sample is a blood sample.

10. The method of claim 1, wherein the patient sample is a biopsy of the targeted tissue or organ.

11. The method of claims 9 or 10, wherein the samples are subjected to flow cytometry cell sorting to identify the armed and labeled cells by phenotyping.

12. The method of claim 11, wherein the samples are taken at different time intervals after reinfusion of the stem cells to track the location of the armed and labeled cells.

13. The method of claim 12, wherein the numbers of armed and labeled cells at a particular time interval and/or *in vivo* location are quantitatively assessed by comparing the number of armed and labeled cells that were reinfused with the number

of armed and labeled cells present in a sample at the particular time interval and/or *in vivo* location by phenotyping the cellular population using flow cytometry.

14. The method of claim 13, wherein blood samples and target tissue samples taken from a patient at a particular time interval and quantitatively assessed using flow cytometry, is indicative of *in vivo* homing progress of armed and labeled stem cells to target tissues.

15. A method of treating a patient suffering from cancer, comprising the steps of:

(a) isolating peripheral blood mononuclear cells from a patient suffering from cancer;

(b) activating of T cells by *ex vivo* stimulation with soluble anti-CD3 monoclonal

antibody;

(c) arming of unactivated and/or activated T cells with bispecific antibodies capable of binding to the T cell receptor complex of a T cell, and to tumor-associated antigens on a tumor cell, under conditions wherein;

(i) bispecific antibody binds to said T cells, tumor cells, and Fc-receptor positive cells,

(ii) activation of said T cells by said antibody binding to the tumor target,

(iii) redirection of said T cells and Fc-receptor positive cells to said tumor cells,

(iv) destruction of said tumor cells by said activated and armed T cells; and,

(d) binding of a labeled secondary antibody specific for the Fc region of the bispecific antibody; or,

(e) directly labeling the bispecific antibody with a detectable marker; and,

(f) reinfusing the armed and labeled activated T cells into a patient.

16. The method of claim 15, wherein the bispecific antibody is comprised of two monoclonal antibodies.

17. The method of claim 15, wherein each of the specificities of the bispecific antibody are directed to a tumor antigen and the T cell receptor complex.

18. The method of claim 17, wherein the bispecific antibody is comprised of monoclonal antibodies directed to any tumor associated antigen.

19. The method of claim 17, wherein the anti T cell receptor monoclonal antibody component of the bispecific antibody is directed against CD3 of the T cell receptor complex.

20. The method of claim 16, wherein secondary antibody, binding to the Fc region of the bispecific antibody, is fluorescently labeled.

21. The method of claim 16, wherein the bispecific antibody is directly fluorescently labeled.

22. The method of claim 16, wherein the armed and labeled T cells are redirected to the tumor antigens.

23. The method of claims 16 through to 22, wherein samples are taken at different time intervals after reinfusion of the T cells to track the location of the armed and labeled T cells.

24. The method of claim 23, wherein the numbers of armed and labeled cells at a particular time interval and/or *in vivo* location are quantitatively assessed by comparing the number of armed and labeled cells that were reinfused with the number of armed and labeled cells present in a sample at the particular time interval and/or *in vivo* location by flow cytometry.

25. The method of claim 23, wherein blood samples and target tissue samples taken from a patient at a particular time interval and quantitatively assessed using flow cytometry, is indicative of *in vivo* homing progress of armed and labeled T cells to target tumors.

26. A method for tracking cells *in vivo* at any desired location, the method comprising:

- isolating and purifying cells from a subject; and,
- providing a chemically heteroconjugated bispecific antibody with a binding site specific for cellular antigen and a binding site specific for a target antigen in any location in a patient; and,
- arming the isolated cells with the bispecific antibody under conditions wherein;
 - (i) the bispecific antibody binds to a specific antigen on the isolated cell; and,
 - (ii) the second antigenic binding site of the bispecific antibody is free to bind to a target antigen; and,
 - (iii) binding of a labeled antibody to the Fc region of the bispecific antibody; or,
 - (iv) fluorescently labeling the bispecific antibody thereby a secondary labeled antibody is not required; and,
- (d) reinfusing the armed and labeled cells into a patient; and,
- (e) tracking the armed and labeled cells by extracting samples from the patient at different time intervals; and,
- (f) identifying the armed and labeled cells using flow cytometry cell sorting; and,
- (g) identifying the armed and labeled cells by immunohistochemical staining or other methods to detect the primary antibody on the cells in various target tissues such as bone marrow, spleen, liver, pancreas, lungs, neural tissue, gastrointestinal track, heart, vascular endothelium.

27. The method of claim 26, wherein the isolated cells are bone marrow cells.
28. The method of claim 26, wherein the isolated cells are hematopoietic stem cells.
29. The method of claim 26, wherein the isolated cells are erythroid stem cells.
30. The method of claim 26, wherein the isolated cells are cells of the immune system.
31. The method of claims 26 through 30, wherein the bispecific antibody binds to a specific ligand of the desired cell.
32. The method of claim 31, wherein the bispecific antibody is directed to a specific antigen on a tissue, organ, or cells.
33. The method of claim 31, wherein trafficking and homing of the armed and labeled cells is detectable by a fluorescent label using flow cytometry.
34. The method of claims 1, 15, 26 or 33, wherein the fluorescent label is selected from the group consisting of green, red, blue, green, cyan, and yellow.
35. The method of claim 34, wherein the isolated cells are transformed with nucleic acid molecules which encode for fluorescent proteins.
36. The method of claim 35, wherein the fluorescent protein is green fluorescent protein.

37. The method of claim 35, wherein the fluorescent protein is enhanced green fluorescent protein.

38. The method of claim 35, wherein the fluorescent protein is red fluorescent protein.

39. A composition comprising: isolated and purified cells, a vector encoding for a bispecific antibody and a fluorescent protein, wherein the isolated cells are transformed with the vector.

40. The composition of claim 39, wherein the isolated cell is a stem cell.

41. The composition of claim 40, wherein the vector is further comprised of oligonucleotides encoding complementary mRNA to specific target mRNA which codes for cell surface antigens.

42. The composition of claim 41, wherein the complementary mRNA inhibits the cell surface expression of cell surface antigens involved in autoimmune or inflammatory diseases.

43. The composition of claim 42, wherein the isolated cell expresses the bispecific antibody on its surface.

44. The composition of claim 43, wherein the isolated cell is targeted to a specific location in vivo.

45. The composition of claim 44, wherein the isolated cell differentiates into the mature cell of the targeted location and does not express the cell surface antigen involved in autoimmune disease or inflammatory disease.

46. The composition of claim 45, wherein the isolated cell is used to provide therapy to a patient suffering from or susceptible to autoimmune and/or inflammatory diseases.

47. The composition of claim 46, wherein the autoimmune disease is rheumatoid arthritis.

48. The composition of claim 46, wherein the autoimmune disease is diabetes.

49. The method of claims 1, 15, 26 or 33, wherein isolated and purified cells are used in functional assays.

50. The method of claims 1, 15, 26 or 33, the functional assays are determined by the cell type and desired cell property.

51. The method of claim 50, wherein the isolated and purified cell is a lymphocyte.

52. The method of claim 51, wherein the functional assay is a T cell assay.

53. The method of claim 51, wherein the functional assay is an ELISA, RIA.

54. The method of claim 51, wherein the functional assay is a cytokine assay.

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